Paper No. 41

# UNITED STATES PATENT AND TRADEMARK OFFICE

## BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BORIS MASINOVSKY,
WILLIAM M. GALLATIN, and
PAUL J. SIMMONS



Appeal No. 2001-1732
Application No. 08/448,649

ON BRIEF

Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

## DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 30 through 33, all the claims remaining in the application. Claim 30 is representative of the subject matter on appeal and reads as follows:

30. A method of blocking interaction between a bone marrow stromal cell expressing VCAM-1 and a cell expressing VLA-4, which comprises administering an antibody to VCAM-1 in an amount effective to decrease VCAM-1-mediated adhesion between the bone marrow stromal cell and the cell expressing VLA-4.

Claims 30 through 33 stand rejected under 35 U.S.C. § 112, first paragraph, on written description and enablement grounds. The examiner does not rely upon any evidence in support of either rejection. We reverse both rejections.

## Background

Vascular cell adhesion molecule-1 (VCAM-1) has as one ligand the β1-integrin, VLA-4. Specification, page 8, lines 34-36. Monoclonal antibodies are known which will bind to human VCAM-1, e.g., mAb 6G10 produced by hybridoma ATTC No. HB10519. Id., page 4.

The claimed invention is based upon appellants' discovery that a receptor for VCAM-1, VLA-4 is expressed at high levels on bone marrow cells bearing the CD34 antigen. Id., page 17. Appellants "infer that adhesive interactions within the bone marrow between hemopoietic stem cells and/or progenitor cells and stromal elements may be mediated by the binding of VLA-4 and the antigen recognized by 6G10." Id. As previously discussed, the "antigen recognized by 6G10" is VCAM-1.

## Discussion

1. Written Description.

The examiner's position is summarized as follows:

> [T]he rejection of record [is] maintained [since] there does not appear to be written support for blocking hemopoietic cell-stromal cell interactions with VCAM-1-specific antibodies nor is there written support how the skilled artisan would use such procedures. The inhibition of adhesion mediated by VCAM-1-specific antibodies as disclosed in the specification as filed is directed towards inhibiting lymphocyte adhesion to inhibit GVHD for example and not towards inhibiting hemopoietic stem and progenitor

> cell adhesion to bone marrow stromal cells to peripheralize/mobilize said hemopoietic cells, as encompassed and asserted by appellant[s].

Examiner's Answer, page 4, 5th paragraph.

In reviewing the matter, we find that the original disclosure of this application provides adequate written descriptive support for the invention set forth in claims 30-33. As seen from claim 30, the claimed invention is directed to a method of blocking interaction between a bone marrow stromal cell expressing VCAM-1 and a cell expressing VLA-4. The method is implemented by administering an antibody to VCAM-1 in an amount effective to decrease VCAM-1-mediated adhesion between the bone marrow stromal cell and the cell expressing VLA-4. The specification explicitly states that the "antigen recognized by mAb 6G10 is expressed on human bone marrow stromal cells in vitro especially after induction with IL-4 and/or TNF." Specification, page 17. Again, the "antigen recognized by mAb 6G10" is VCAM-1. The specification also explicitly states that VLA-4, a major receptor for VCAM-1, is "expressed at high levels on bone marrow cells bearing the CD34 antigen." Id. The specification also explicitly states that mAb 6G10 binds specifically with VCAM-1. See, e.g., specification, page 8.

Since VCAM-1 binds VLA-4 and monoclonal antibody 6G10 binds VCAM-1, the original disclosure describes the method required by claim 30 on appeal. In other words, the specification of this application adequately describes that the interaction between a bone marrow stromal cell expressing VCAM-1 (the antigen recognized by

mAb 6G10) and a cell expressing VLA-4, e.g., a bone marrow cell bearing the CD34 antigen, may be blocked by administration of an antibody to VCAM-1.

In reviewing the examiner's position on appeal it appears that the examiner has misconstrued the claims. The examiner states "there is insufficient written support for this key element of the claimed invention, drawn to methods of blocking the interaction between a bone marrow stromal cell expressing VCAM-1 and a cell expressing VLA-4 encompassing hemopoietic stem and progenitor cells for the purpose of peripheralizing/ mobilizing or harvesting hemopoietic stem and progenitor cells for bone marrow transplantation in the specification as filed." Examiner's Answer, page 8. However, the claims on appeal do not require that the interaction between a bone marrow stromal cell expressing VCAM-1 and a cell expressing VLA-4 be for any particular purpose. Claim 30 only requires blocking interaction between those two cells. That step is adequately described in the original disclosure of this application.

2. Enablement.

The examiner's enablement rejection is difficult to review since it is not premised upon a fact-based analysis of the factors set forth in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

As we understand the examiner's position, it appears that it is also based upon an incorrect reading of the claims. For example, the examiner states:

> The application as filed does not provide guidance and direction on 'how to use' anti-VCAM-1 to block any VCAM-1-mediated adhesion, regardless of the type of cells involved, and, in particular, to release bone marrow progenitor cells from the marrow to the peripheral blood or to

> mobilize hemopoietic cells in order to peripheralize and to harvest hemopoietic cells for bone marrow transplantation.
>
> Therefore, the specification as filed does not provide any guidance on 'how to use' the VCAM-1 specific antibodies in the manner encompassed or intended by the claimed methods, as argued by appellant[s] in conjunction with the Torok-Storb and Papayannoupoulo declarations of record (see below for details). The specification is drawn to inhibiting lymphocyte adherence not to inhibiting hemopoietic stem and progenitor cell adherence. The disclosure does not provide sufficient direction or guidance as to which therapeutic conditions and what therapeutic endpoints are would [sic] be appropriate for the claimed methods.

Examiner's Answer, page 5, paragraphs 6 and 7.

The examiner appears to be misreading the claims since claim 30 only requires blocking interaction between a bone marrow stromal cell expressing VCAM-1 and cell expressing VLA-4. Apart from requiring that the antibody used to effect this process be administered in an amount effective to decrease the VCAM-1-mediated adhesion between the cells, the claim 30 does not require any of the therapeutic methods which appear to be of concern to the examiner.

On this record, the examiner has not established a prima facie case of lack of enablement.

Summary

We have reversed both of the rejections made by the examiner under 35 U.S.C. § 112, first paragraph. Since we have determined that the examiner has not made a prima facie case of lack of written description or enablement, we have not considered the various declarations relied upon by appellants in the briefing.

The decision of the examiner is reversed.

REVERSED

Sherman D. Winters
Administrative Patent Judge

William F. Smith
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

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